DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

Office of the Chief Mediator and Ombudsman
5600 Fishers Lane, HF-7
Rockville, MD 20857

September 18, 1997

Edward L. Korwek
Hogan & Hartson, L.L.P.
Columbia Square
555 Thirteenth Street, MW
Washington, DC 20004-1109

Dear Mr. Korwek:

This is to confirm that your September 11, 1997 letter to this office concerning the regulatory classification of Periostat® (doxycycline hyclate capsules) has been referred to the Center for Drug Evaluation and Research for further action. As discussed in our telephone conversation last Tuesday, we view your letter as raising policy and legal issues that are beyond the scope of 21 C.F.R. Part 3, and are appropriately the province of CDER management.

For further information, please contact Dr. Murray Lumpkin, Deputy Director for Review Management, CDER, at 301-594-5400.

Sincerely Yours,

Steven H. Unger
Deputy, Office of the Chief Mediator
and Ombudsman

cc: Dr. Murray Lumpkin